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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dipak K. Banerjee, *et al.*	Group Art Unit: 1623
Application No.: 09/779,447	Examiner: Howard V. Owens, Jr.
Filed: February 9, 2001	**CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8(a)**
For: METHODS FOR INHIBITING ANGIOGENESIS	

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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- Reply Brief

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November 8, 2006

By: Elena M. Jiménez

UPR-0100

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Dipak K. Banerjee, *et al.*	Group Art Unit: 1623
Application. Number: 09/779,447	Examiner: Howard V. Owens, Jr.
Filed: February 9, 2001	**REPLY BRIEF**
For: METHODS FOR INHIBITING ANGIOGENESIS	

This is a reply to the Examiner's Answer Brief mailed September 29, 2006. For reasons further set forth below, it is respectfully submitted that the Examiner's rejections should be reversed.

I. The Prior Art Relied upon by the Examiner Teaches away from *in Vivo* Applications.

The Examiner argues, without citation to any support in any reference, that "the prior art has recognized levels at which tunicamycin toxicity occurs." (Examiner's Answer Brief, p. 6.) Based upon this unsupported assertion, the Examiner argues that "one skilled in the art would [therefore] know what dosage levels would be inappropriate." (*Id.*) In fact, the prior art teaches that any dosage level would be inappropriate for a patient because it would cause brain damage.

When determining the teachings of a prior art reference, it must be viewed as a whole and its teachings considered in context. When viewed this way, Tiganis *et al.* clearly teach away from the use of tunicamycin to treat a patient. In the last paragraphs of this reference the author's concluded their findings. They explained:

> Consequently first pass metabolism of tunicamycin in the liver was insufficient to prevent systemic delivery of tunicamycin to the intestine.

> In view of this finding and because endothelial cells have proved to be so vulnerable to tunicamycin *in vitro*, the damage to brain microvessels in tunicamycin-treated animals is likely to be due to a direct action of tunicamycin on the endothelial cells. (Page 199, lines 17-24.)

Contrary to the Examiner's unsupported assertion, this does not teach "what dosage levels would be inappropriate;" it teaches that any dosage levels would be inappropriate because brain damage is obviously not an acceptable side effect in the treatment of a patient.

II. The Prior Art Relied upon by the Examiner Nowhere Teaches the Resting Period Expressly Recited in Each of the Claims on Appeal.

Against the teachings of the prior art, the subject application discloses that tunicamycin can be administered to a patient. In order to do so safely, the subject application teaches the administration of the drug, followed by a resting period, then followed again by the administration of the drug. Each of the claims on appeal include this further element.

The examiner contends that one skilled in the art would "determine[] the optimum dosage for each patient, based upon a variety of physical and metabolic factors." (Examiner's Answer Brief, p. 4.) Even accepting this hindsight, it fails to address the language of the claims. These do not merely recite a dosage level but expressly recite a resting period during which no dose is given in order to safely administer the drug to a patient, which might otherwise cause brain damage.

Moreover, the examiner's hindsight is not enabled by the prior art. Aside from unsupported assertions, the examiner provides no citation to any prior art reference that teaches a safe dose of tunicamycin for treating patients, let alone the resting period expressly recited in each of the claims on appeal.

PATENT

III. *In re Brana* Is Inapposite to the Issue on Appeal.

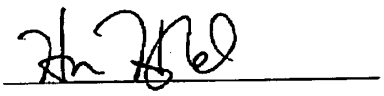
The examiner argues that *In re Brana*, 51 F.3d 1560, is determinative in this appeal. (Examiner's Answer Brief, p. 5.) In fact, this case is inapposite to the issue in this case. *In re Brana* involved a rejection under 35 U.S.C. § 112 ¶ 1. Specifically, the examiner in that case had rejected the claims at issue for failure to disclose specific utility.

In this case, the examiner has made no rejection under 35 U.S.C. § 112 (or under § 101 for that matter). The application is fully supported by an exhaustive, sixty-six (66) page specification. While the examiner criticizes the amount of *in vivo* data included in the specification, there are no rejections under 35 U.S.C. § 101 or 112. Had the examiner made such a rejection during prosecution, it could have been addressed in further detail by a declaration or other evidence.

The only issue in this application is whether the prior art fairly teaches the use of tunicamycin to treat angiogenesis in a patient as set forth in the claims. For the reasons set forth above and in applicants' appeal brief, the examiner's arguments are supported only by hindsight. It is respectfully submitted that when viewed as a whole the prior art clearly teaches away from these claims.

Respectfully submitted,

November 8, 2006

By: 

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